



09/753,128

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Y. FREEDLAND
Serial Number: 09/753,128
Filed: December 30, 2000
For: SPLIT-NUT PRECISION FASTENERS
Art Unit: 3743
Examiner: Kathryn P. ODLAND

Hon. Commissioner of Patents
P. O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT

Sir:

In response to an Advisory Action mailed April 19, kindly amend the instant application as follows:

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TECHNOLOGY CENTER R3700

On page 23, following line 30, please add:

“FIG. 30’ is a side view of a modified split nut and snap ring assembly being used as a suture nut. The halves of the split nut are separated;

FIG. 31’ is a side view of the suture nut of FIG. 30’, wherein the snap ring is engaged 10 more tightly with the split nut thereby forcing its halves together.”

FIG. 32’ is a bottom plan view of the assembly of FIG. 30’.

FIG. 33’ is a bottom plan view of the assembly of FIG. 31’.

FIG. 34’ is a cross-sectional perspective view of the snap ring of FIGS. 30’-33’.

FIGS. 35’-37’ are perspective views of a suture nut in operation.”

(PCT/IB00/00364, Page 9, lines 7-14)

On Page 48, following line 21, please add:

“The suture nut provides a very efficient method for applying compressive and fixating force by its button shape on the suture. The suture nut presses against the surrounding tissue surface. Since the suture nuts sections are fully cut longitudinally, they transmit the pressure of the encircling band relatively evenly along their entire length with their interface along the suture. As it is preferably made from relatively non-deforming bioabsorbable materials, the suture nuts sections transmit the full force of the encircling band to the suture, making the Suture Nut a strong fastener. The Suture Nut can be installed through small laparoscopic incisions and placed in small areas of the body using fine instrumentation. It saves operating room time as the Suture Nut installs much faster on the sutures than it takes to tie a knot in suture. Further, the Suture Nuts position against the tissue can be gauged much more precisely than suture knots.

“FIG. 30’ depicts a suture nut assembly (58). The suture nut assembly comprises two partial nut sections (58a, 58b) and a snap ring (60). The suture nut includes a bore (58c) that is generally not threaded. Moreover, the surfaces that define the bore (58c) at the inside of the suture nut are friction surfaces that are designed to grasp suture material.

“The suture nut is generally used as follows. The band (60) is engaged with the lower groove (59a) such that the sections (58a, 58b) are adjacent yet spaced from one another. A suture (61) is placed within the bore (58c) and the Suture Nut is slid along the suture until it sits against the tissue that is to be secured. The snap ring is slid from the lower groove (59a) to the upper groove (59b), thereby causing the sections (58a, 58b) to clamp the suture (61).

“FIGS. 35’-37’ depict a suture nut as it is generally used to facilitate closure of an incision in a body tissue. A suture nut (58) is clamped onto a first end of the suture (61), which has a needle (63) at its second end. The needle and suture are threaded through the tissue adjacent an incision (62) in any manner used by a surgeon. The suture is pulled so that the suture nut abuts the tissue surface. The surgeon then continues to stitch the tissue to close the incision. Once the final stitch is made, the suture is tightened to close the incision and the second suture nut (64) is clamped onto the portion of the suture that is just exterior to the skin and is part of the last stitch. The suture is then cut to size, and the excess suture and attached needle are removed.

“In an alternate embodiment, the suture nut includes a single enlarged bore, or a pair of small bores, adapted to receive two suture ends. In this embodiment, a single suture nut can be used to grasp two different portions of a suture simultaneously. The paired holes can be separated as desired. Alternatively, the single enlarged hole can be oval or otherwise shaped to simultaneously accommodate two suture portions within it.

“The Suture Nut is preferably constructed from one or more of the combinations of polymers used in dissolvable implants, some of which were noted above...”

(PCT/IB00/00364, Page 17, line 7 to Page 18, line 27)

“... that can be made to dissolve more rapidly when in contact with a catalytic agent.”

(PCT/IB00/00364, Page 6, lines 3-6)

Following Page 62 of Figures, please add pages labeled 11’/13’ and 12’/13’ from PCT/IB00/00364.

Please note that to distinguish between numbers in the incorporated Figs. and the instant patent Figs., a prime sign (‘) has been added to all numbers on the incorporated pages.

Attached are amendments in accordance with format requirements of the USPTO.

COMMENTS

Examiner has raised the following objections:

U.S. Patent 6,162,234, included by reference, would not lead one with ordinary skill in the art to conclude that the split nut of the instant invention would contact tissue. Additionally, the description of the instant application does not support various claims in the instant invention, including:

- a) The instant invention contacts a tissue;
- b) The instant invention includes a suture;
- c) An embodiment of the instant invention includes two elements;
- d) An embodiment of the instant invention is dissolvable;
- e) In the lower position, band B contacts tissue; and
- f) In the upper position, band B does not contact tissue.

Applicant respectfully disagrees with Examiner. The telephonic communication of February 28, 2004, (see INTERVIEW SUMMARY of May 10, 2004) established some distinguishing features of the instant application over Seegmiller et al., U.S. Patent No. 5, 525, 013 based on priority document U.S. Patent 6,162,234:

Seegmiller et al. teaches a split jacket fastener that surrounds a multi-strand cable that serves to prevent the strands from flaying radially outward. The forward surface of the split jacket fastener specifically does *not* compress against a surface.

During the telephonic communication, it was agreed upon that one of the distinguishing features of the instant invention is a split nut having a forward surface that *compresses against a tissue surface*.

Examiner's statement that that the instant invention is "directed to the medical art" apriori concedes that the instant invention contacts a tissue surface.

To ensure acceptance of the instant application, Applicant has taken the additional step of amending the instant application by incorporating relevant sections of priority document PCT/IB00/00364, "Precision Tension Bolt", filed March 28, 2000 (that has since published as WO 01/49189). Priority of PCT/IB00/00364 is stated on Page 1, lines 2-3 of the instant application:

"The present application claims the priority of earlier filed International patent application serial no. PCT/IB00/00364 filed March 28, 2000;"

While Examiner has expressed reluctance to allow amendments of the instant application using foreign filings incorporated by reference, PCT/IB00/00364 is a *priority* document to the instant application. Regarding the incorporation of *priority* documents, the MPEP 608.01(p)[1B] states: "The same policy concern does not apply where [the]... foreign application is to establish an earlier filing date."

PCT/IB00/00364, sections of which are incorporated in the instant application, provides support for the above-noted objections in addition to that provided by U.S. Patent 6,162,234:

a) The instant invention contacts a tissue;

"The suture nut presses against the surrounding tissue surface."

(PCT/IB00/00364, Page 17, lines 9-10)

b) The instant invention includes a suture;

"Since the suture nuts sections are fully cut longitudinally, they transmit the pressure of the encircling band relatively evenly along their entire length with their interface along the suture."

(PCT/IB00/00364, Page 17, lines 11-12)

c) An embodiment of the instant invention includes two elements;

"In an alternate embodiment, the suture nut includes a single enlarged bore, or a pair of small bores, adapted to receive two suture ends."

(PCT/IB00/00364, Page 18, lines 19-20)

d) An embodiment of the instant invention is dissolvable;

"The Suture Nut is preferably constructed from one or more of the combinations of polymers used in dissolvable implants, some of which were noted above..."

(PCT/IB00/00364, Page 18, lines 26 - 27)

"...that can be made to dissolve more rapidly when in contact with a catalytic agent."

(PCT/IB00/00364, Page 6, lines 5-6)

e) In the lower position, band B contacts tissue

FIG. 30'

(PCT/IB00/00364)

f) In the upper position, band B does not contact tissue.

FIG. 31'

(PCT/IB00/00364)

Favorable consideration is earnestly solicited. Applicant is responding pro se under "Revocation of Existing Power Of Attorney and Election to Persecute Pro Se" included herein. In the event Examiner cannot issue a notice of allowance, please use the address listed below for sending correspondence to the applicant.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Y. Freedland", written over a horizontal line.

Y. FREEDLAND

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